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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/821,078	04/08/2004	Robert A. Davis	56630US007	1677
32692 7590 01/18/2008 3M INNOVATIVE PROPERTIES COMPANY PO BOX 33427 ST. PAUL, MN 55133-3427			EXAMINER HAND, MELANIE JO	
			ART UNIT	PAPER NUMBER
			3761	
			NOTIFICATION DATE	DELIVERY MODE
			01/18/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

LegalUSDocketing@mmm.com
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Office Action Summary

Application No.

10/821,078

Applicant(s)

DAVIS ET AL.

Examiner

Melanie J. Hand

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 November 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 58-96 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 58-96 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 11/8/07.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 8, 2007 has been entered.

Response to Arguments

2. Applicant's arguments, see Remarks, filed November 8, 2007, with respect to the rejection(s) of claim(s) 58-60 and 62-75 under 35 U.S.C. 102 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of a different interpretation of a previously applied prior art reference. Briefly, applicant sets forth in claim 58 that at least one of the inner and outer layers is substantially impermeable to ethylene oxide, and sets forth in claim 62 that the outer layer comprises polyester, which is taught explicitly by Dischler, and the inner layer comprises a layer of polyolefin, which is also taught by Dischler (specifically polypropylene and polyethylene), Dischler teaches the same materials for the instant inner and outer barrier lamina, thus at least one of the inner and outer barrier lamina taught by Dischler is inherently substantially impermeable to ethylene oxide.

Claim Rejections - 35 USC § 102/103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Claims 58-60, 62-78, 83-89 and 91-96 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Dischler.

With respect to **Claims 58,64-67,69,70,73,74**: Dischler teaches a single-dose syringe 24 comprising cylindrical syringe body 62 (container) defining an interior volume, wherein said container is comprised of at least one polymeric layer (wall) that does not contain metal lamina. The interior volume defined by syringe body 62 contains second blister chamber 42 that houses injection prep fluid such as alcohol (skin antiseptic composition). Second blister chamber 42 is closed by cap 64 comprising fill port 52 (vent having vent orifice-claim 65), seal 50 (vent seal) and break zone 46 (collectively, the dispensing means). Cap 64 is joined to body 62 by thin web 44 (vent seal layer-claim 67) can be broken, allowing said antiseptic composition in second chamber 42 to escape and be delivered to a skin surface (claim 66). The polymeric layers of body 62 serve as barriers and are comprised of materials consistent with the stability, storage time and compatibility of the contents, and are therefore impervious to both liquid and vapor forms of said antiseptic. With regard to the limitation "at least one barrier layer that is substantially impermeable to ethylene oxide", applicant sets forth in claim 62 that the outer layer comprises polyester, which is taught explicitly by Dischler, and sets forth in claim 63 that the inner layer comprises a layer of polyolefin, which is also taught by Dischler (specifically polypropylene and polyethylene). Dischler teaches the same materials for the instant inner and outer barrier lamina, thus at least one of the inner and outer barrier lamina taught by Dischler is inherently substantially impermeable to ethylene oxide. When the structure or composition

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recited in the reference is substantially identical to that of the claimed invention, claimed properties or functions are presumed to be inherent. See MPEP §2112-2112.01. A prima facie case of either anticipation or obviousness has been established when the reference discloses all of the limitations of a claim except for a property or function and the examiner cannot determine whether or not the reference inherently possesses properties that anticipate or render obvious the claimed invention but has a basis for shifting the burden of proof to the applicant. See *In re Fitzgerald*, 205 USPQ 594 (CCPA 1980).

With respect to **Claim 62**: Dischler teaches polyester as a polymer acceptable for construction of the polymer lamina of body 62.

With respect to **Claims 63,72,75**: Dischler teaches polypropylene and polyethylene as materials for the barrier layers, which are polyolefins.

With respect to **Claim 68**: Dischler teaches that the barrier lamina are flexible.

With respect to **Claim 71**: Dischler teaches that the polymer lamina are attached to one another via additional heat sealable polymer (heat activated adhesive) lamina therebetween that function also as barrier lamina.

With respect to **claim 76**: The device of Dischler meets substantially all of the claim limitations of claim 76. Dischler is silent regarding the percent of weight lost by the container based upon the weight of the skin composition. When the structure or composition recited in the reference is substantially identical to that of the claims of the instant invention, claimed properties or

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functions presumed to be inherent (MPEP 2112-2112.01). A prima facie case of either anticipation or obviousness has been established when the reference discloses all the limitations of a claim (in this case, a dispenser according to claim 73) except for a property or function (in the present case, percent of weight lost by the container based upon the weight of the skin composition when placed in a convection oven at 60 degrees Celsius for 14 days) and the examiner can not determine whether or not the reference inherently possesses properties that anticipate or render obvious the claimed invention but has a basis for shifting the burden of proof to applicant, as per *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980).

With respect to **claim 77**: The device of Dischler meets substantially all of the claim limitations of claim 76. Dischler is silent regarding a permeability to gaseous ethylene oxide. When the structure or composition recited in the reference is substantially identical to that of the claims of the instant invention, claimed properties or functions presumed to be inherent (MPEP 2112-2112.01). A prima facie case of either anticipation or obviousness has been established when the reference discloses all the limitations of a claim (in this case, in this case, a dispenser according to claim 73) except for a property or function (in the present case, a permeability to gaseous ethylene oxide of 20 mg.hr/cm² or less) and the examiner can not determine whether or not the reference inherently possesses properties that anticipate or render obvious the claimed invention but has a basis for shifting the burden of proof to applicant, as per *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980). The limitation "when determined in accordance with the Gaseous Ethylene Oxide Permeability Test" is given little patentable weight herein.

With respect to **Claim 81**: Dischler teaches a single-dose syringe 24 comprising cylindrical (i.e. tubular) syringe body 62 (container) defining an interior volume, wherein said container is

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comprised of at least one polymeric layer (wall) that does not contain metallic foil lamina. The interior volume defined by syringe body 62 contains second blister chamber 42 that houses injection prep fluid such as alcohol (skin antiseptic composition). Second blister chamber 42 is closed by cap 64 comprising fill port 52 (vent having vent orifice-claim 65), seal 50 (vent seal) and break zone 46 (collectively, the dispensing means). Cap 64 is joined to body 62 by thin web 44 (vent seal layer-claim 67) can be broken, allowing said antiseptic composition in second chamber 42 to escape and be delivered to a skin surface (claim 66). The polymeric layers of body 62 serve as barriers and are comprised of materials consistent with the stability, storage time and compatibility of the contents, and are therefore impervious to both liquid and vapor forms of said antiseptic. With regard to the limitation "wherein the container exhibits permeability to gaseous ethylene oxide of 20 mg/hr/cm² or less", applicant sets forth in claim 62 that the outer layer comprises polyester, which is taught explicitly by Dischler, and sets forth in claim 63 that the inner layer comprises a layer of polyolefin, which is also taught by Dischler (specifically polypropylene and polyethylene). Dischler teaches the same materials for the instant inner and outer barrier lamina, thus at least one of the inner and outer barrier lamina taught by Dischler inherently possesses a permeability to ethylene oxide within the claimed range. When the structure or composition recited in the reference is substantially identical to that of the claimed invention, claimed properties or functions are presumed to be inherent. See MPEP §2112-2112.01. A prima facie case of either anticipation or obviousness has been established when the reference discloses all of the limitations of a claim except for a property or function and the examiner cannot determine whether or not the reference inherently possesses properties that anticipate or render obvious the claimed invention but has a basis for shifting the burden of proof to the applicant. See *In re Fitzgerald*, 205 USPQ 594 (CCPA 1980).

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With respect to **claim 83**: The one or more flexible walls free of metallic foil layers taught by Dischler comprise an inner layer facing the interior volume and an outer layer facing away from the interior volume. The polymeric layers of body 62 serve as barriers and are comprised of materials consistent with the stability, storage time and compatibility of the contents, and are therefore impervious to both liquid and vapor forms of said antiseptic. With regard to the limitation "wherein the container exhibits permeability to gaseous ethylene oxide of 20 mg/hr/cm² or less", applicant sets forth in claim 62 that the outer layer comprises polyester, which is taught explicitly by Dischler, and sets forth in claim 63 that the inner layer comprises a layer of polyolefin, which is also taught by Dischler (specifically polypropylene and polyethylene). Dischler teaches the same materials for the instant inner and outer barrier lamina, thus at least one of the inner and outer barrier lamina taught by Dischler inherently possesses a permeability to ethylene oxide within the claimed range. When the structure or composition recited in the reference is substantially identical to that of the claimed invention, claimed properties or functions are presumed to be inherent. See MPEP §2112-2112.01. A prima facie case of either anticipation or obviousness has been established when the reference discloses all of the limitations of a claim except for a property or function and the examiner cannot determine whether or not the reference inherently possesses properties that anticipate or render obvious the claimed invention but has a basis for shifting the burden of proof to the applicant. See *In re Fitzgerald*, 205 USPQ 594 (CCPA 1980).

With respect to **Claim 84**: Dischler teaches polyester as a polymer acceptable for construction of the polymer lamina of body 62.

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With respect to **Claim 85**: Dischler teaches polypropylene and polyethylene as materials for the barrier layers, which are polyolefins.

With respect to **claims 86-88**: Second blister chamber 42 is closed by cap 64 comprising fill port 52 (vent having vent orifice-claim 86) and a seal 50 (vent seal closing the vent orifice) and break zone 46 (dispensing seal).

With respect to **claim 89**: Dischler teaches a single-dose syringe 24 comprising cylindrical syringe body 62 (container) defining an interior volume, wherein said container is comprised of at least one polymeric layer (wall) that does not contain metal lamina. The interior volume defined by syringe body 62 contains second blister chamber 42 that houses injection prep fluid such as alcohol (skin antiseptic composition). Second blister chamber 42 is closed by cap 64 comprising fill port 52 (vent having vent orifice-claim 65), seal 50 (vent seal) and break zone 46 (collectively, the dispensing means). Cap 64 is joined to body 62 by thin web 44 (vent seal layer-claim 67) can be broken, allowing said antiseptic composition in second chamber 42 to escape and be delivered to a skin surface (claim 66). The polymeric layers of body 62 serve as barriers and are comprised of materials consistent with the stability, storage time and compatibility of the contents, and are therefore impervious to both liquid and vapor forms of said antiseptic. With regard to the limitation "at least one barrier layer that is substantially impermeable to ethylene oxide", applicant sets forth in claim 62 that the outer layer comprises polyester, which is taught explicitly by Dischler, and sets forth in claim 63 that the inner layer comprises a layer of polyolefin, which is also taught by Dischler (specifically polypropylene and polyethylene). Dischler teaches the same materials for the instant inner and outer barrier lamina, thus at least one of the inner and outer barrier lamina taught by Dischler is inherently

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substantially impermeable to ethylene oxide. When the structure or composition recited in the reference is substantially identical to that of the claimed invention, claimed properties or functions are presumed to be inherent. See MPEP §2112-2112.01. A prima facie case of either anticipation or obviousness has been established when the reference discloses all of the limitations of a claim except for a property or function and the examiner cannot determine whether or not the reference inherently possesses properties that anticipate or render obvious the claimed invention but has a basis for shifting the burden of proof to the applicant. See *In re Fitzgerald*, 205 USPQ 594 (CCPA 1980).

With respect to **Claim 91**: Dischler teaches polyester as a polymer acceptable for construction of the polymer lamina of body 62.

With respect to **Claim 92**: Dischler teaches polypropylene and polyethylene as materials for the barrier layers, which are polyolefins.

With respect to **claims 93-96**: Second blister chamber 42 is closed by cap 64 comprising fill port 52 (vent having vent orifice) and a seal 50 (vent seal closing the vent orifice) and break zone 46 (dispensing seal).

Claims 59, 61, 79-81, 82, 90 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dischler (693).

With respect to **Claim 59**: Dischler teaches a syringe body 62 having walls comprised of polymeric lamina and therefore teaches that the barrier covers 100% (i.e. at least 60%) (claim 60) of the walls of body 62. Applicant has not established sufficient criticality for having a barrier

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material that covers less than 100%, therefore this limitation is considered an optimization of the surface area of said barrier layer(s). It would be obvious to one of ordinary skill in the art to modify the barrier coverage area to be less than 100% as the blister chambers collectively are not coextensive with said walls and therefore would only need the barrier functionality in the areas adjacent said chambers. Leaving the remainder free of barrier material would facilitate transparency and visual inspection of said syringe.

With respect to **Claims 61,79-81,82,90**: Dischler does not explicitly teach any of the items set forth in claims 61, 79-81, 82, 90, but does teach that second chamber 42 contains an injection prep or other sterilizing fluid, of which povidone (iodine complex) and chlorhexidine digluconate are examples that are well-known in the art, therefore it would be obvious to one of ordinary skill in the art to fill second chamber 42 with povidone with a reasonable expectation of success to accomplish the function of a skin antiseptic composition.

Double Patenting

5. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

6. Claims 81-96 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 24-39 of prior U.S. Patent No. 7, 261,701. This is a double patenting rejection.

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7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 58-80 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 24-39 of U.S. Patent No. 7,261,701. Although the conflicting claims are not identical, they are not patentably distinct from each other because: claim 58 of the instant application recites at least barrier layer that is substantially impermeable to ethylene oxide and claim 24 of the patent recites a container exhibiting permeability to gaseous ethylene oxide of less than 20 mg/hr/cm^2 , which is applicant's disclosed quantitative definition of "substantially impermeable to ethylene oxide". Further, independent claim 73 recites a container comprising one or more polymeric walls and a barrier layer adhered to at least a portion of the exterior of the wall, and independent claims 24 and 32 of the patent recite a container having one or more flexible walls. The claimed barrier layer of the instant application is considered herein to be a flexible wall since applicant sets forth in claim 62 of the instant application that the barrier layer, considered herein to be an additional wall, comprises polyester, which is flexible. Claims 59-72 and 74-79 are identical to claims 25-31 and 33-39, respectively, of the patent.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie J. Hand whose telephone number is 571-272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie J Hand
Examiner
Art Unit 3761

January 10, 2008

TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER

